

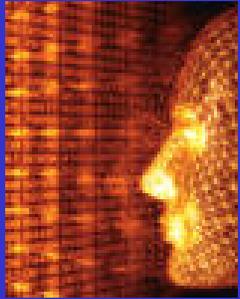
CBER: PDUFA IV Meeting



Jesse L. Goodman, MD, MPH

Director, Center for Biologics Evaluation and Research

11/14/05



Vision for CBER

INNOVATIVE TECHNOLOGY ADVANCING PUBLIC HEALTH

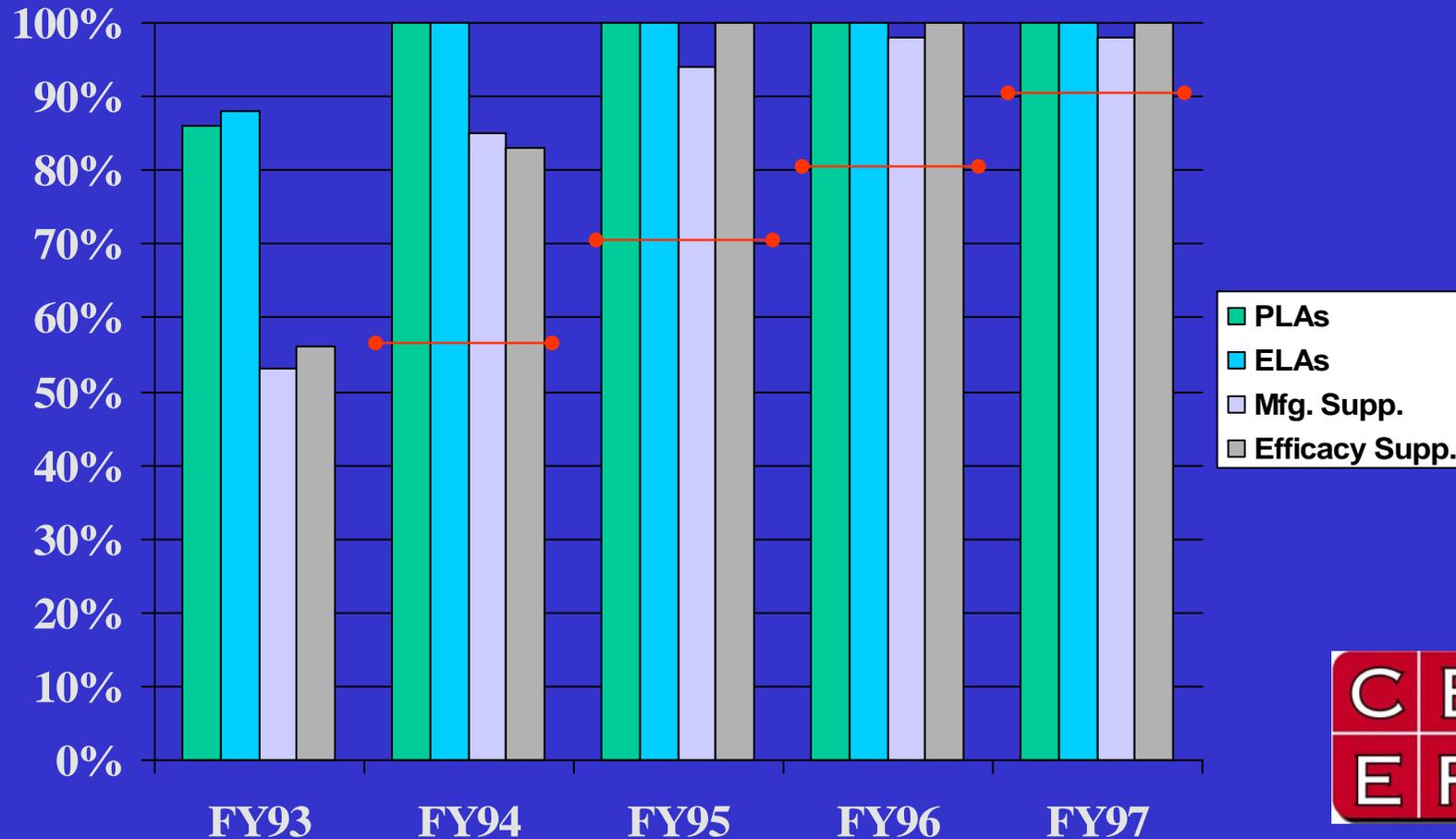
- **Protect and improve public and individual health in the US and, where feasible, globally**
- **Facilitate the development, approval and access to safe and effective products and promising new technologies**
- **Strengthen CBER as a preeminent regulatory organization for biologics**

*PDUFA has provided essential support
all these areas....*



CBER User Fee Review Performance License Applications and Supplements

% of First Actions Within Goal*
for PDUFA I Cohort Fiscal Years 1993-1997

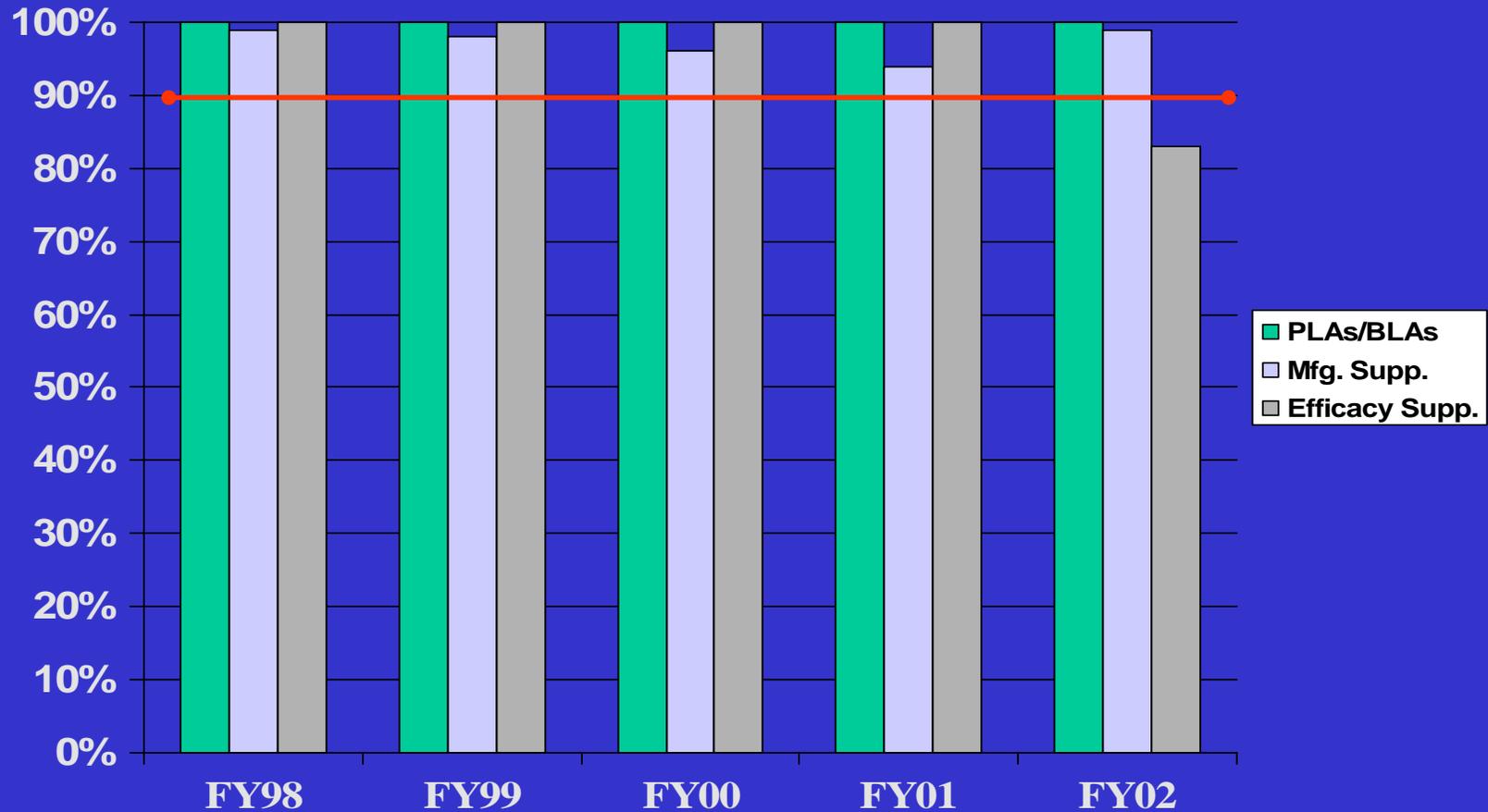


* PDUFA I Performance Goals: FY93=No Goals, FY94=55%, FY95=70%, FY96=80%, FY97=90 (Indicated by Red Lines)
Data for all years complete



CBER User Fee Review Performance License Applications and Supplements

% of First Actions Within Goal*
for PDUFA II Cohort Fiscal Years 1998-2002



•PDUFA II Performance Goal: 90% (Indicated by Red Lines)

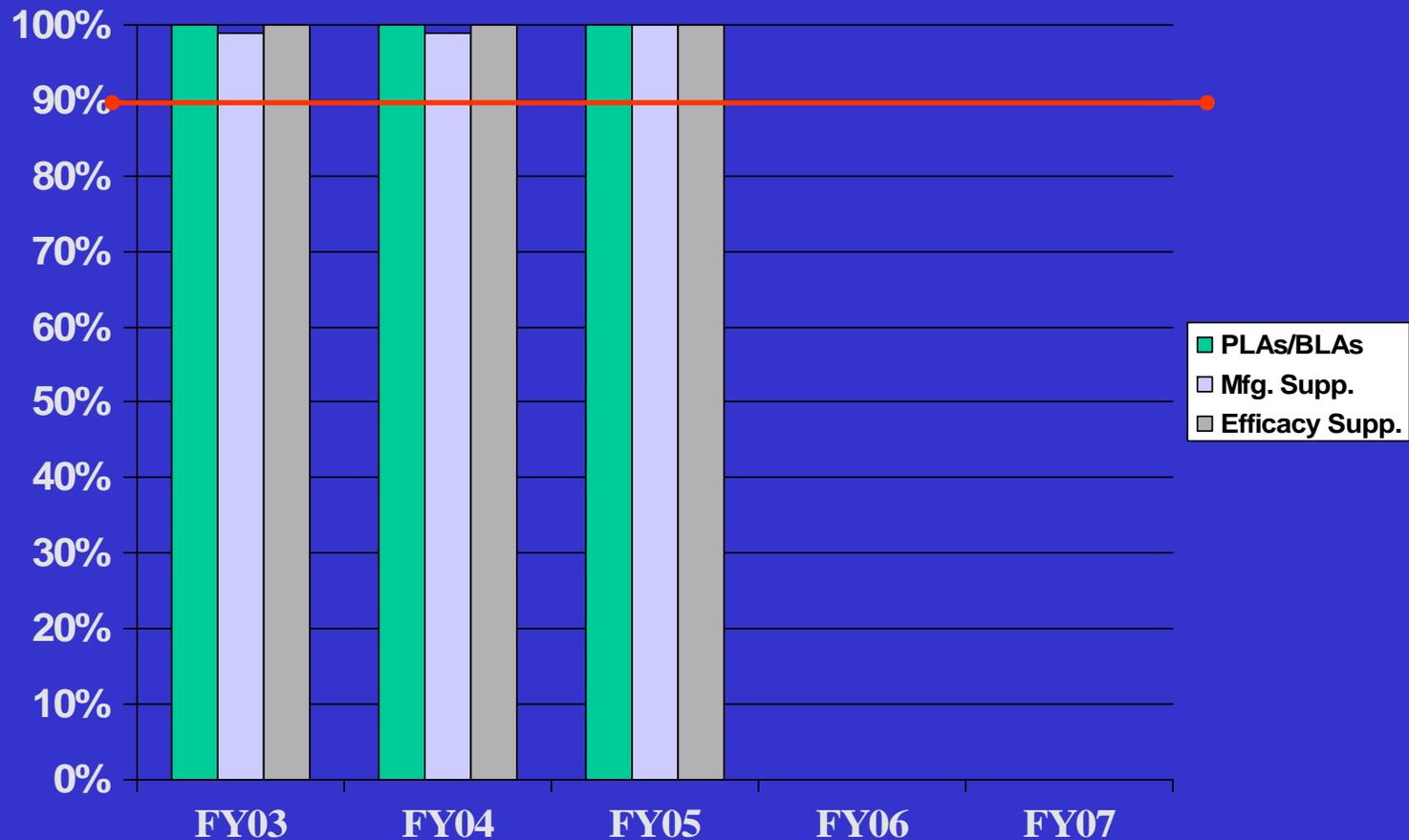
(L-251)RIMS 11/10/05



CBER User Fee Review Performance License Applications and Supplements

% of First Actions Within Goal*

for PDUFA III Cohort Fiscal Years 2003 – 2007



•PDUFA II Performance Goal: 90% (Indicated by Red Lines)

Data as of 10/31/05

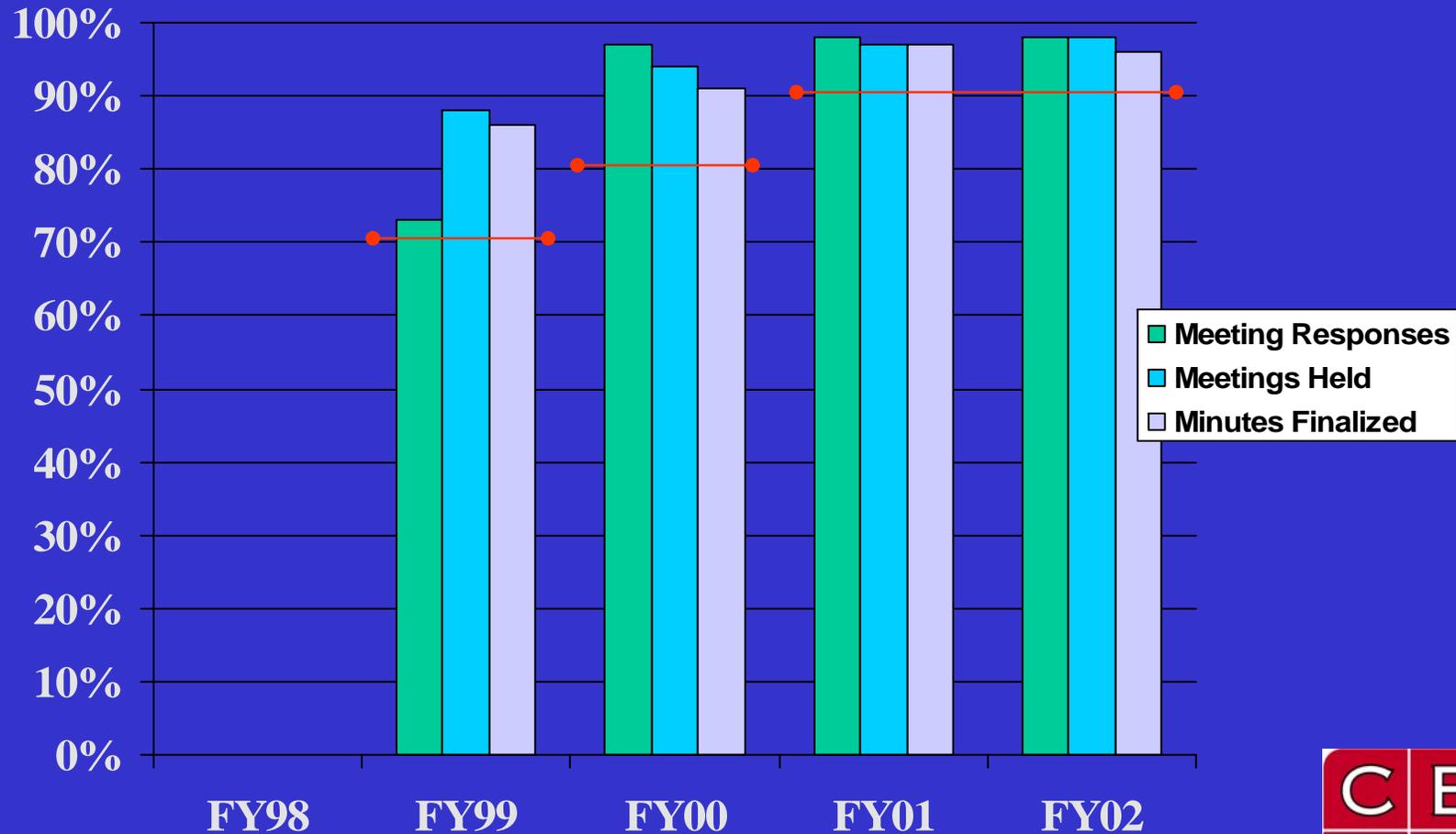
(L-251)RIMS 11/10/05



CBER PDUFA Meeting Management Performance

% Actions Within Goal

for PDUFA II Cohort Fiscal Years 1998-2002



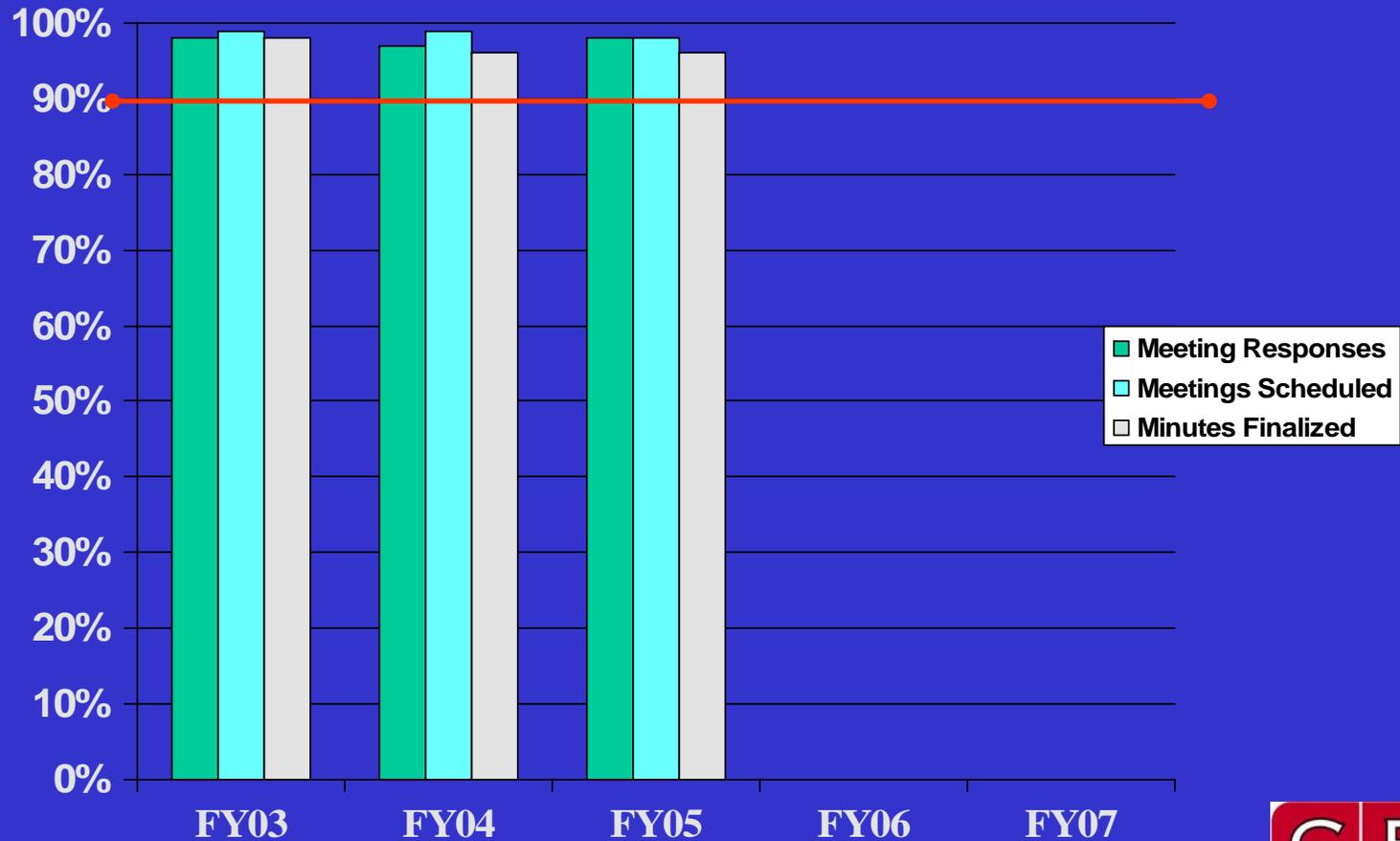
* PDUFA II Performance Goals: FY98=No Goals, FY99=70%, FY00=80%, FY01=90%, FY02=90 (Indicated by Red Lines)
Data for all years complete



CBER PDUFA Meeting Management Performance

% Actions Within Goal

for PDUFA III Cohort Fiscal Years 2003-2007

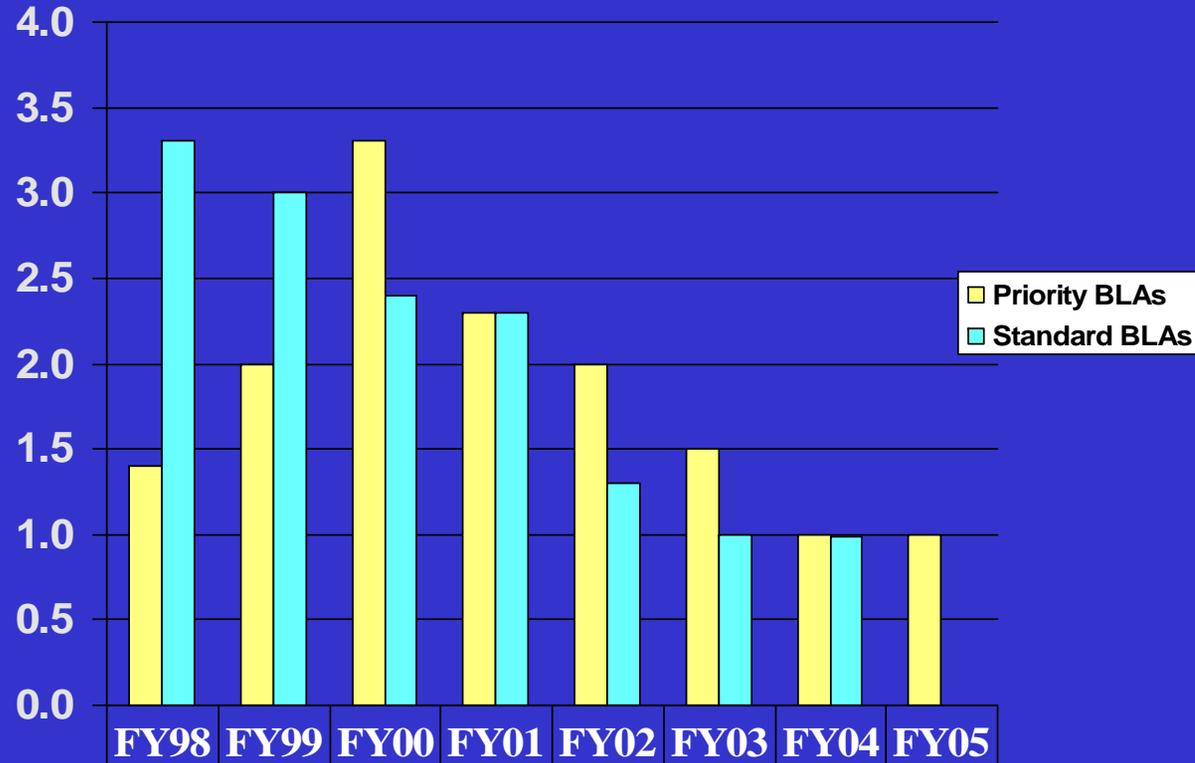


•PDUFA III Performance Goal: 90% (Indicated by Red Lines)



Average Review Cycles for Priority and Standard CBER BLAs

Receipt Cohort Fiscal Years 1998-2005



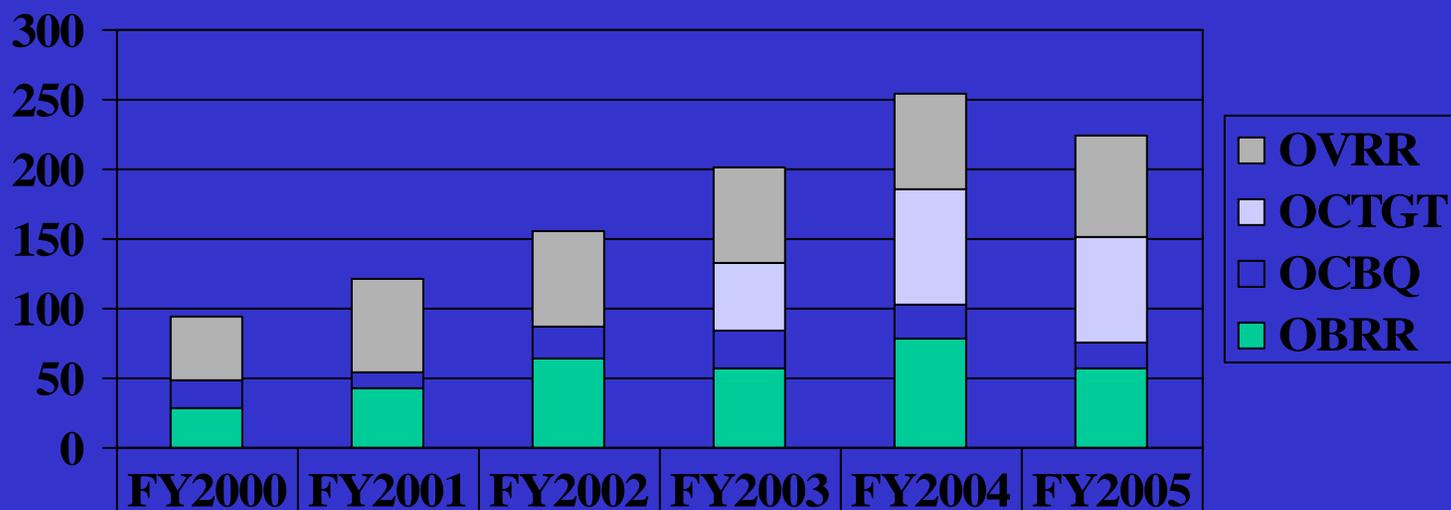
■ Priority BLAs	1.4	2.0	3.3	2.3	2.0	1.5	1.0	1.0
■ Standard BLAs	3.3	3.0	2.4	2.3	1.3	1	1.0	

Data as of September 2005. Average cycles in later years will increase as the 'slower' BLAs are approved.



Current CBER Offices

PDUFA Meetings FY00-FY05



	FY2000	FY2001	FY2002	FY2003	FY2004	FY2005
OVRR	46	68	69	69	69	74
OCTGT				49	83	75
OCBQ	19	11	23	27	25	19
OBRR	29	43	64	57	78	57

Selected Recent BLA Approvals

- **Fluarix - Influenza Virus Vaccine (8/05)**
 - **Accelerated approval**
- **Menactra - Meningococcal (Serogroups A, C, Y & W-135) Conjugate Vaccine (1/05)**
- **ProQuad - MMRV (9/05)**
- **Adacel - Tdap (adol. & adult) (6/05)**
- **Boostrix - Tdap (adolescent) (5/05)**

Selected Recent BLA Approvals

- **Immune Globulin IV products**
(8/03, Gammunex; 12/03, Flebogamma;
5/04, Octagam; 4/05 Gammagard Liquid)
- **Rhophylac (Rho D Immune Globulin) 2/04**
- **Vaccinia Immune Globulin IV Human (2/05)**
– Accelerated approval/Fast track designation
- **Vaccinia Immune Globulin IV Human (5/05)**
– Accelerated approval/Fast track designation

Selected Recent BLA Efficacy Supplement Approvals

- **Havrix – Hepatitis A Vaccine (10/05)**
- **VAQTA – Hepatitis A Vaccine (8/05)**
- **NovoSeven- Coagulation Factor VIIa
(8/05)**

PDUFA Summary

- PDUFA has helped to support an expert and efficient managed review process at CBER
- An important feature is intensive interactions with sponsors during product development
- The result is earlier access to safe, effective and innovative products, including lifesaving vaccines and blood products that are essential to our medical care and public health systems and to our nation's preparedness



BIOHAZARD

