

# United States Animal Health Association Biologics & Biotechnology Committee

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Inspection and Compliance



Safeguarding Animal Health

# Priority Activities

- Efficiency of operations
- Inspections
- Guidance documents
- Quality management – ISO 17025
- Service to NCAH

# Staffing Update

- Organizational chart
- Section Leader – Program Information Management and Security (PIMS)
- Biologics Epidemiologist
- Product Manager
- Targeted recruitment efforts

# Information Management

- National Centers for Animal Health
  - Newly formed Information Management Unit
- Consolidated April 29, 2007
- NVSL Information Resource Management Services (IRMS) staff, NADC Information Technology, Library and Visual Services staffs
- Developed Customer Service Plan and a Service Level Agreement to define and detail services provided

# Information Management

- Several Major Information System Security Initiatives
- Working through procurement constraints
- More Efficient alignment of staff – training
- Coordination with APHIS, VS and ARS CIO staffs

# Automated Information Management System (AIMS)

- Timeline Release 1 of Phase II
  - Phase II project restructured October 07
  - Business Requirements finalized
  - Functional Requirements under review
  - New contractor
  - September 2008 projected completion
- Enhancements
  - Increased tracking capability
  - User friendly - web application
  - Technological advancements

# Automated Information Management System (AIMS)

- Future Challenges
  - APHIS Form 2008 currently a Level 3 application
    - STILL No solution from USDA/APHIS for Level 3 applications
  - Signatures/Authentication
    - STILL No solution from USDA/APHIS for electronic signatures

# Continuity of Operations Plan (COOP)

- Mission Critical Business Processes
  - Re-Evaluating MCBP's
    - Business Resumption Plans
    - Disaster Recovery Plans
    - Living Disaster Recovery Planning System (LDRPS)
  - Contractor to work in aligning with VS COOP
    - Scanning of Outlines of Production
      - Special Outlines - Completed
      - Outlines of Production – on hold/resource issue
- VS Business Recovery Plans
  - National Select Agent Registry
    - Maintain tertiary roles at CVB



# 2007 Goal for CVB

## Certification to ISO 9001:2000 standards

Effective business management system to ensure:

- Quality product
- Customer satisfaction

Emphasizing:

- Individual accountability
- Process improvement based on measurable objectives

# Scope of ISO 9001:2000 Certification

- Review of prelicensing data
- Issuance of establishment and product permits and licenses
- Inspection of facilities
- Production of testing aids
- Evaluation of product
- Writing of standards and procedures for product release
- Providing compliance oversight for firms producing or distributing Veterinary Biologics in the United States

# Goal for 2008

## Accreditation to ISO 17025:2005

Accreditation to ISO 17025:2005 standards provides verification of laboratory competency for testing

The CVB scope of the ISO 17025:2005 accreditation will cover tests conducted using Supplemental Assay Methods (SAMs)

# Administrative Inspection Review (AIR)

- Starting 4<sup>th</sup> Year for AIRs
- Benefits:
  - Firms able to schedule resources
  - Enhances compliance from biologics firms
  - Determine need for Inspections
- Expanded to Include Permittees
- Working to Prioritize Program Information Requests

# Export Activities

- Continued Work to Provide and Coordinate Information between Industry, International Services and Foreign Countries
- Items of Interest
  - India's restrictions on U.S live poultry products
  - Taiwan's restrictions on live biological products
  - MAPA Visit to CVB concerning Adverse Event Reports
  - Exporting recombinants to China
  - Exports to Mexico containing IAO's

# Inspection Activities

- Continue to partner with APHIS/VS/NCIE on facility inspections for Select Agent registrations
- Staffing resources (6/16 vacant inspector positions)
- Increased inspection efficiency

# Primary Sources of Compliance Issues- Investigations

- Potency/Stability/Safety
- Unlicensed manufacturing
- Advertising
- Repackaging/Packaging/Labeling

# Pharmacovigilance

- VICH Harmonization activities
  - Meeting held in Washington DC – Sept 2007
    - Signed Guidelines:
      - Management of Adverse Event Reports (GL24)
      - Controlled Lists of Terms (GL30)
      - Electronic Standards for Transfer of Data (GL35)
      - Data Elements for Submission of Adverse Event Reports (GL42)
- New Proposed Rules needed for implementation of Guidelines

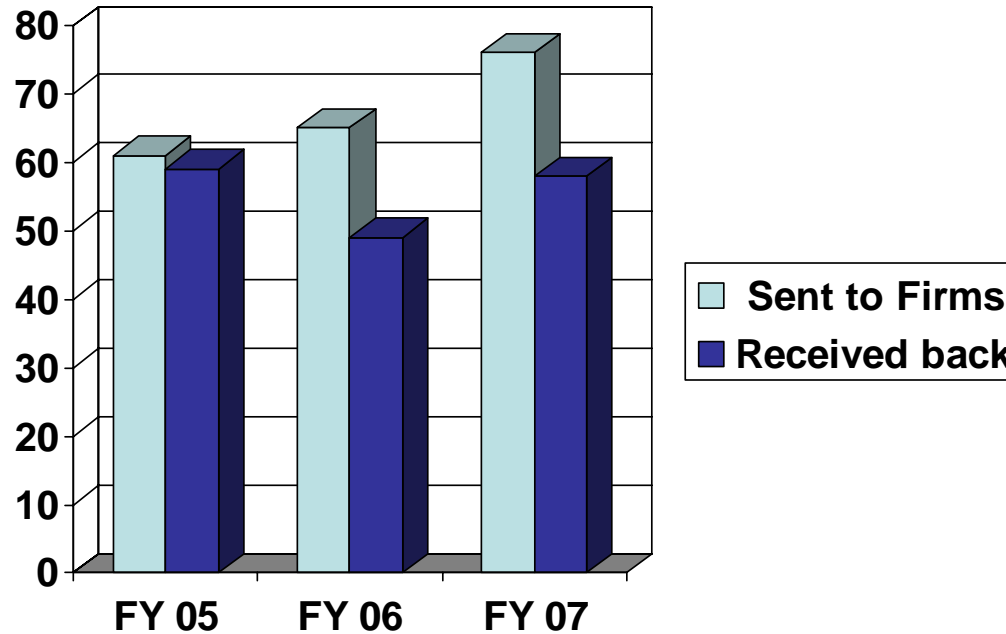


# Resources

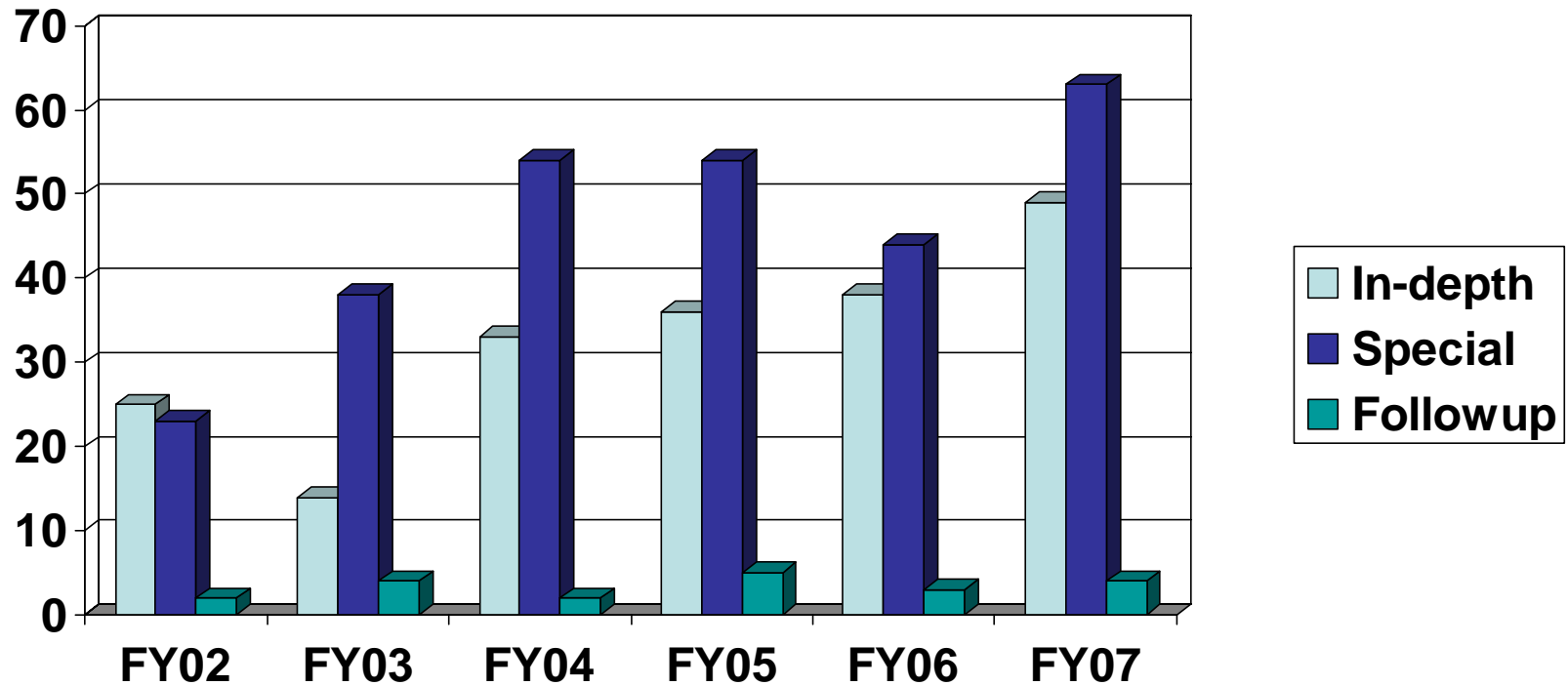
- Looking at utilization of staff
  - Inspections and Investigations will remain priority
  - Turnaround times for review and response may be delayed for:
    - Manufacturing deviations prior to release
    - Firm requests (extensions of dating, reprocessing)
    - Facility document reviews/approvals
    - Ultimately – serial release process and timlieness may be reviewed

# Administrative Inspection Review (AIR)

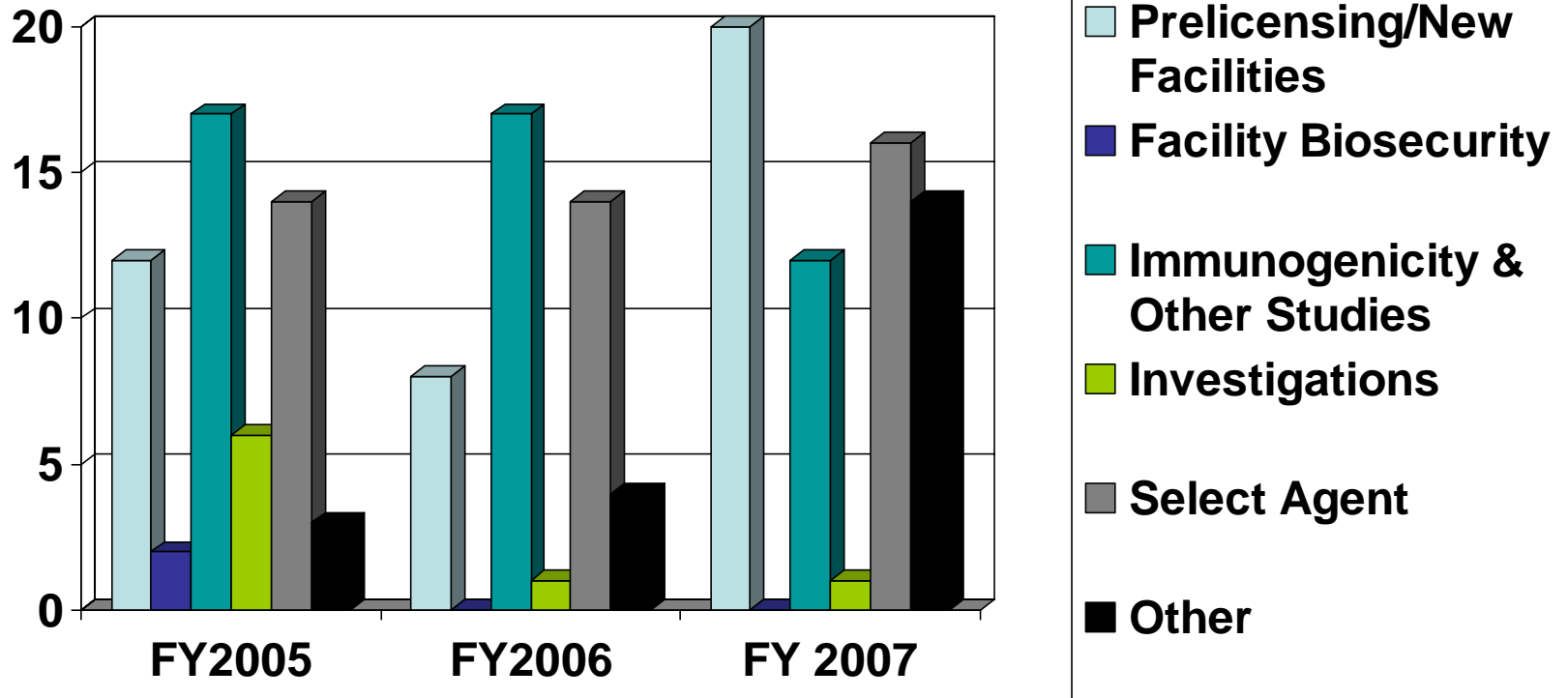
## Activity per Year



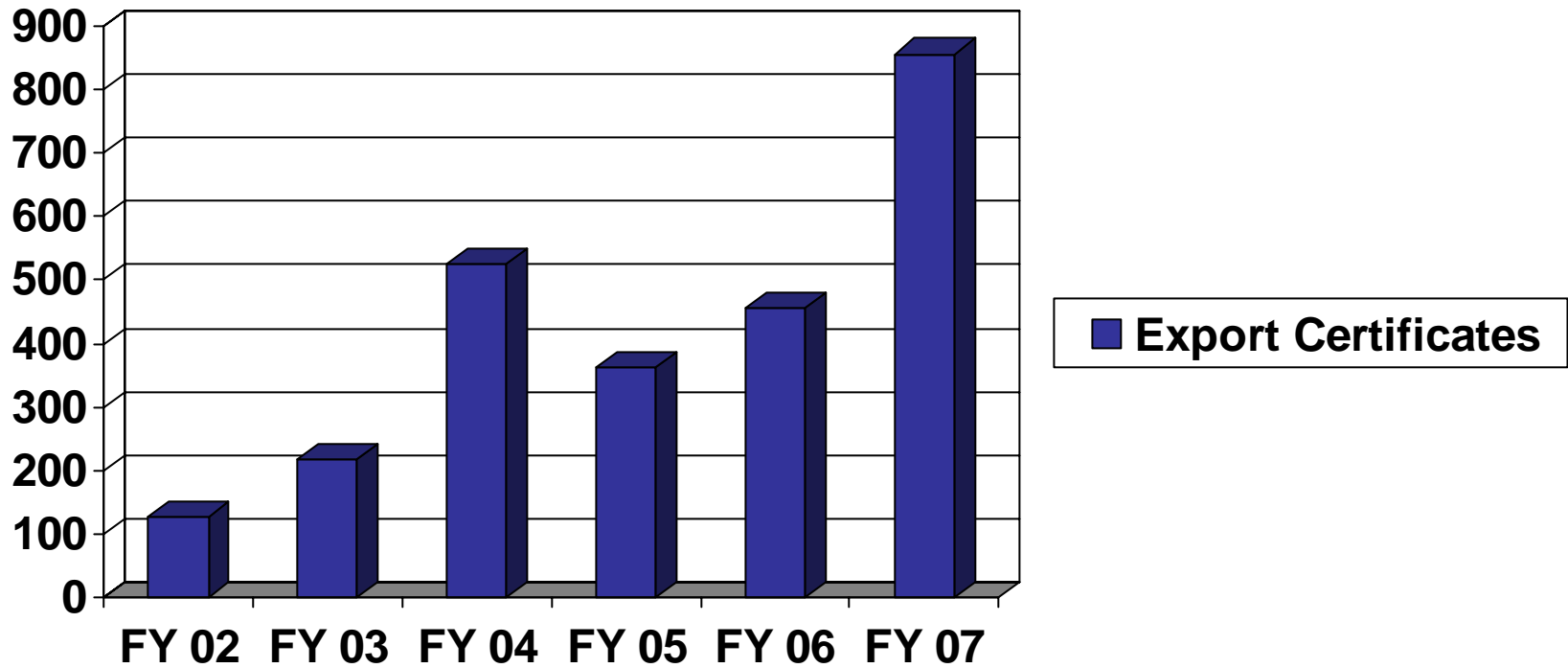
# Inspections



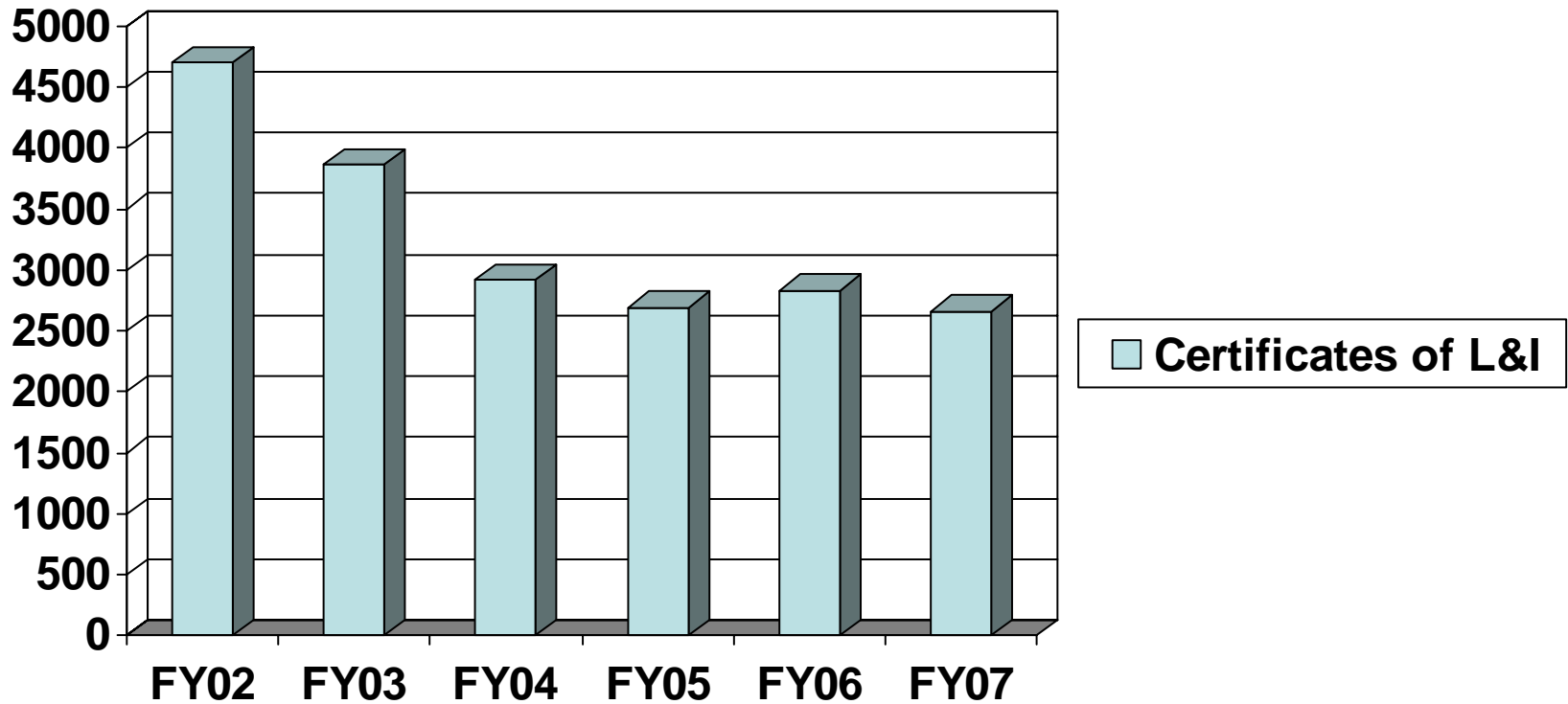
# Special Inspections



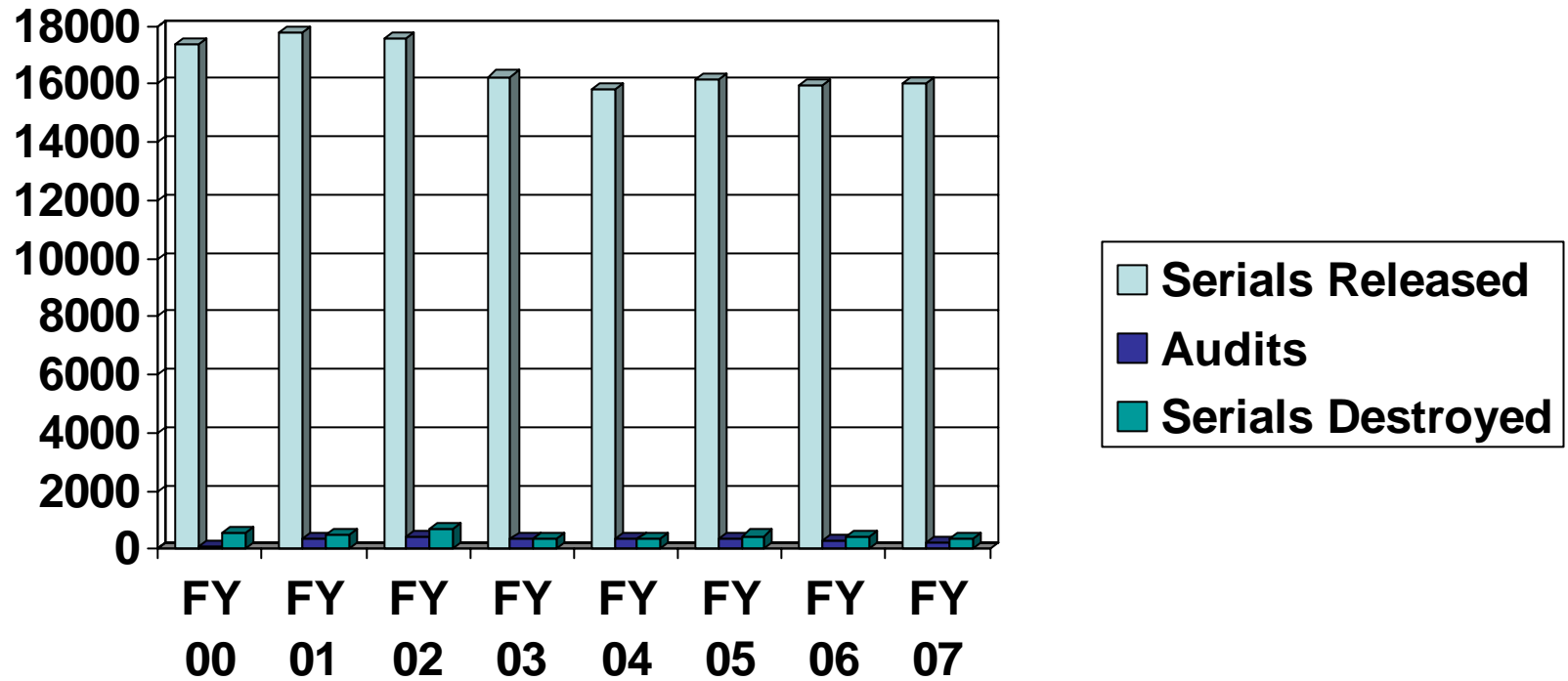
# Export Activities by Serial



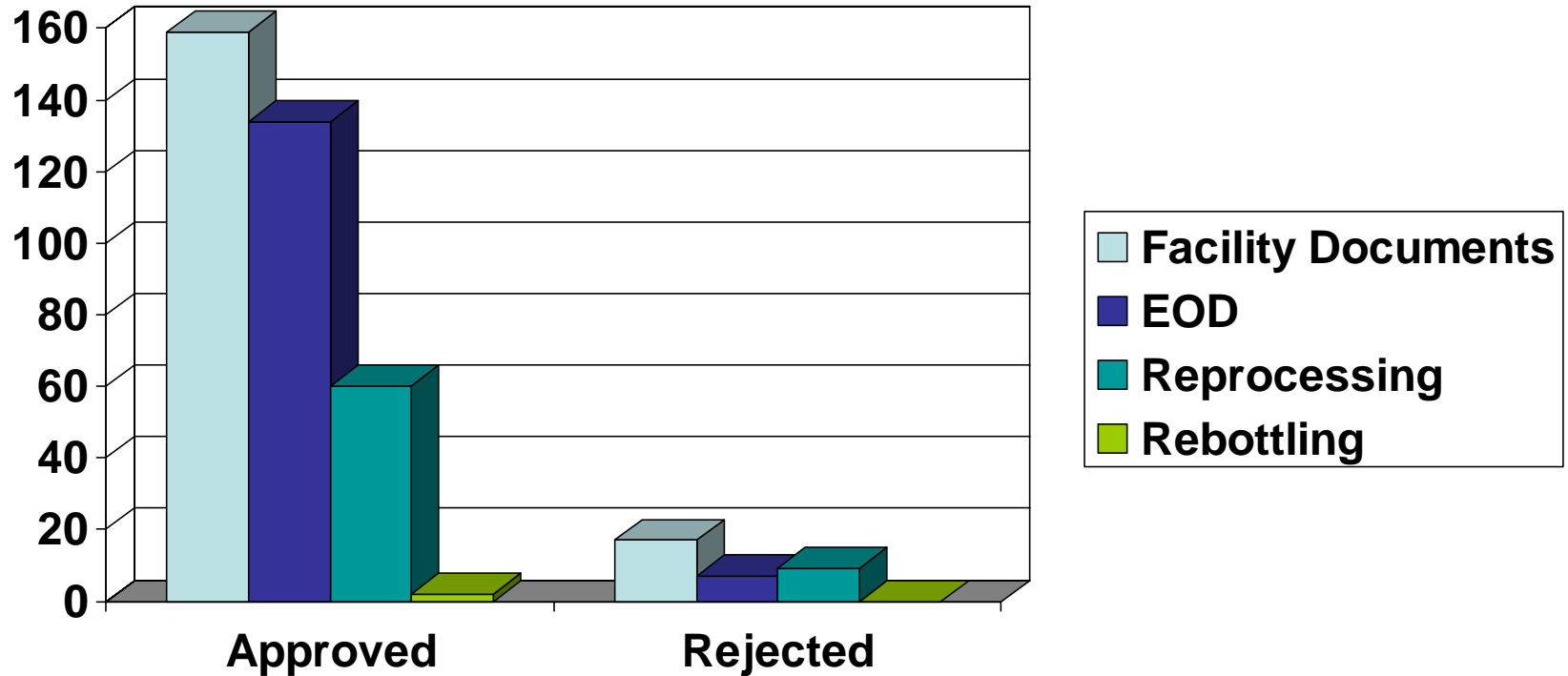
# Export Activities by Product



# Serial Release Activities

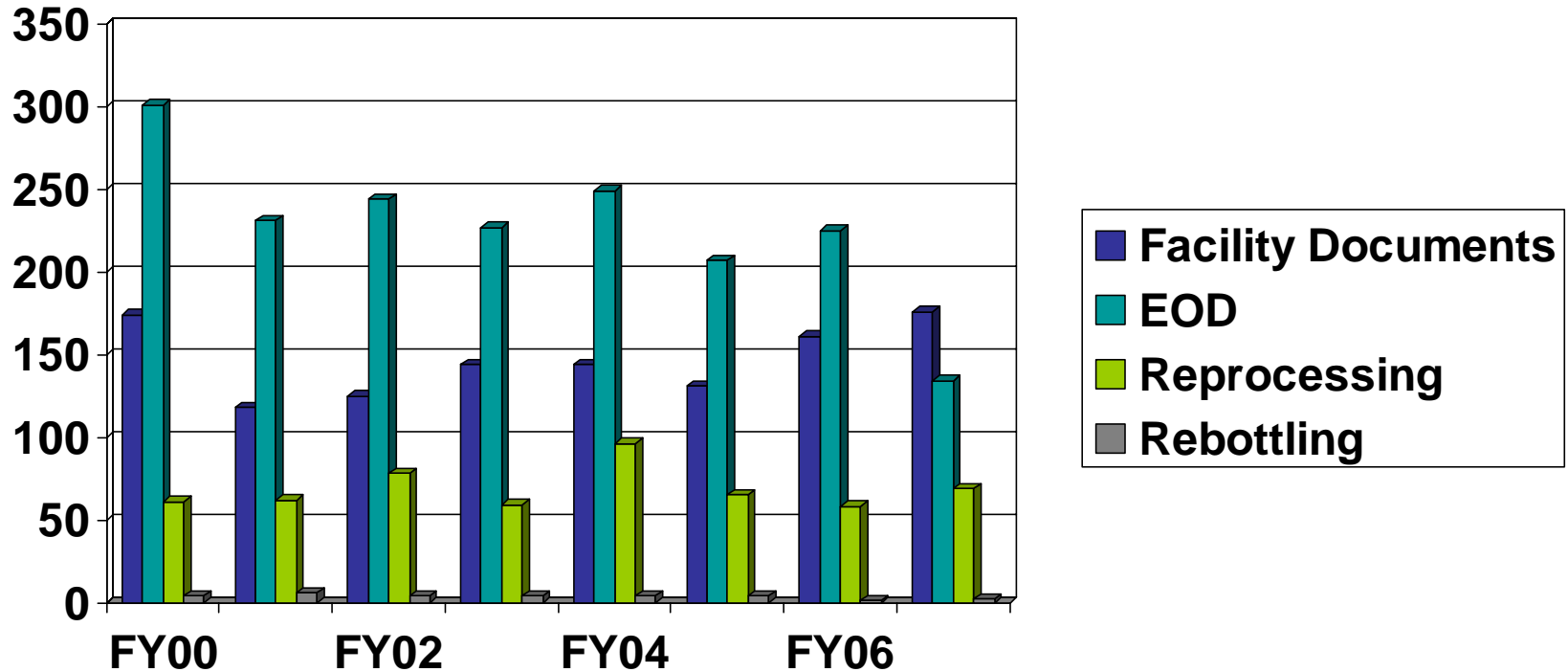


# Product Inspection Activities – FY 07

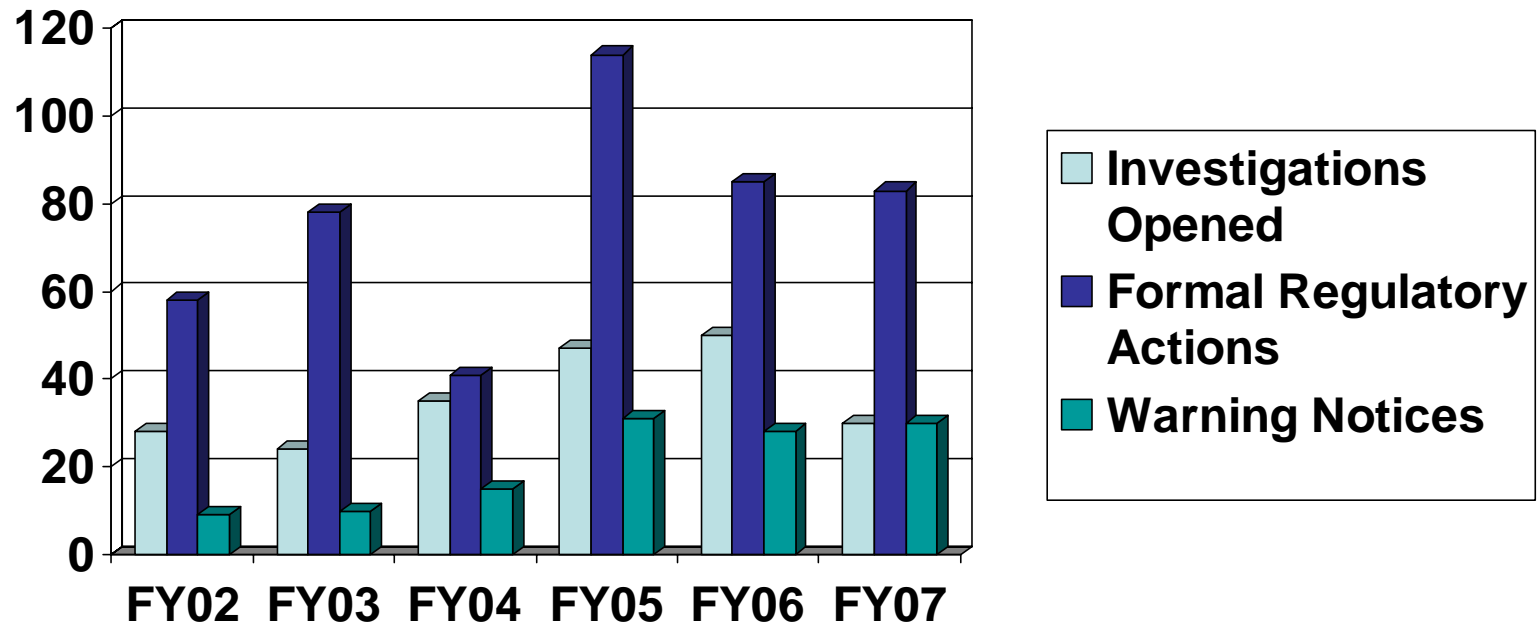




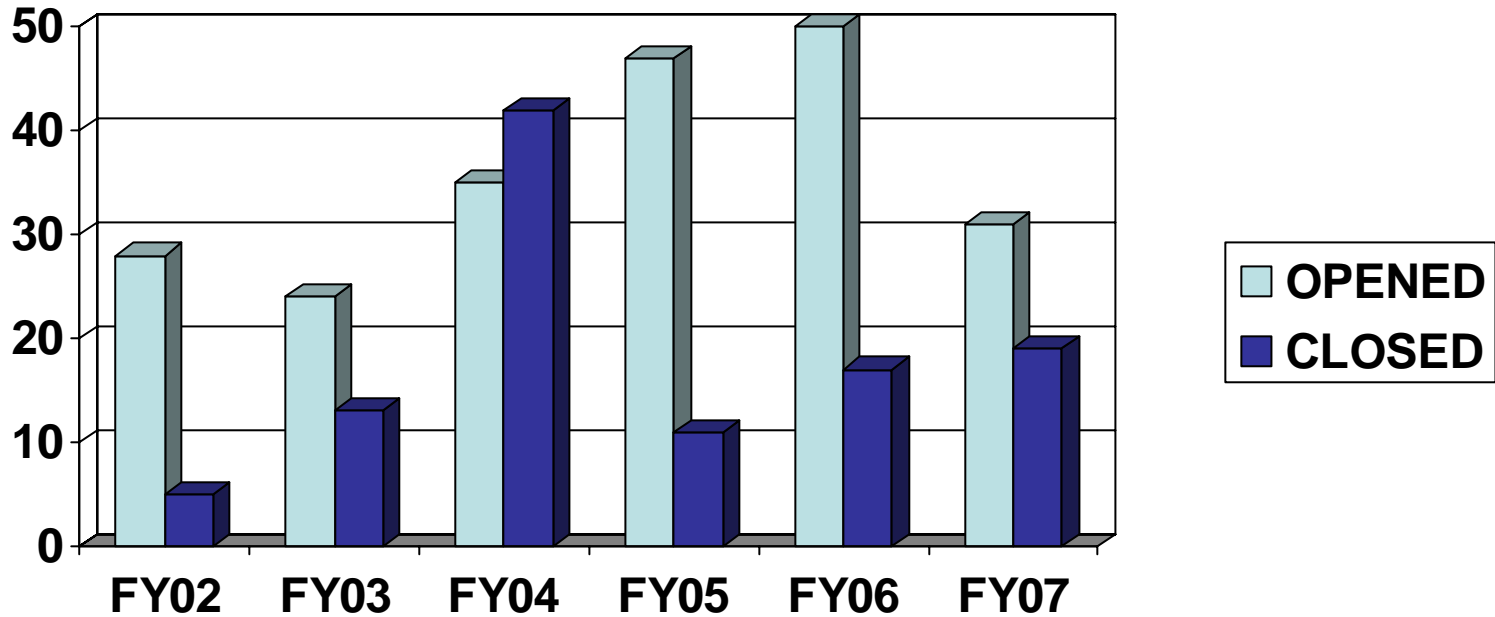
# Product Inspection Activities



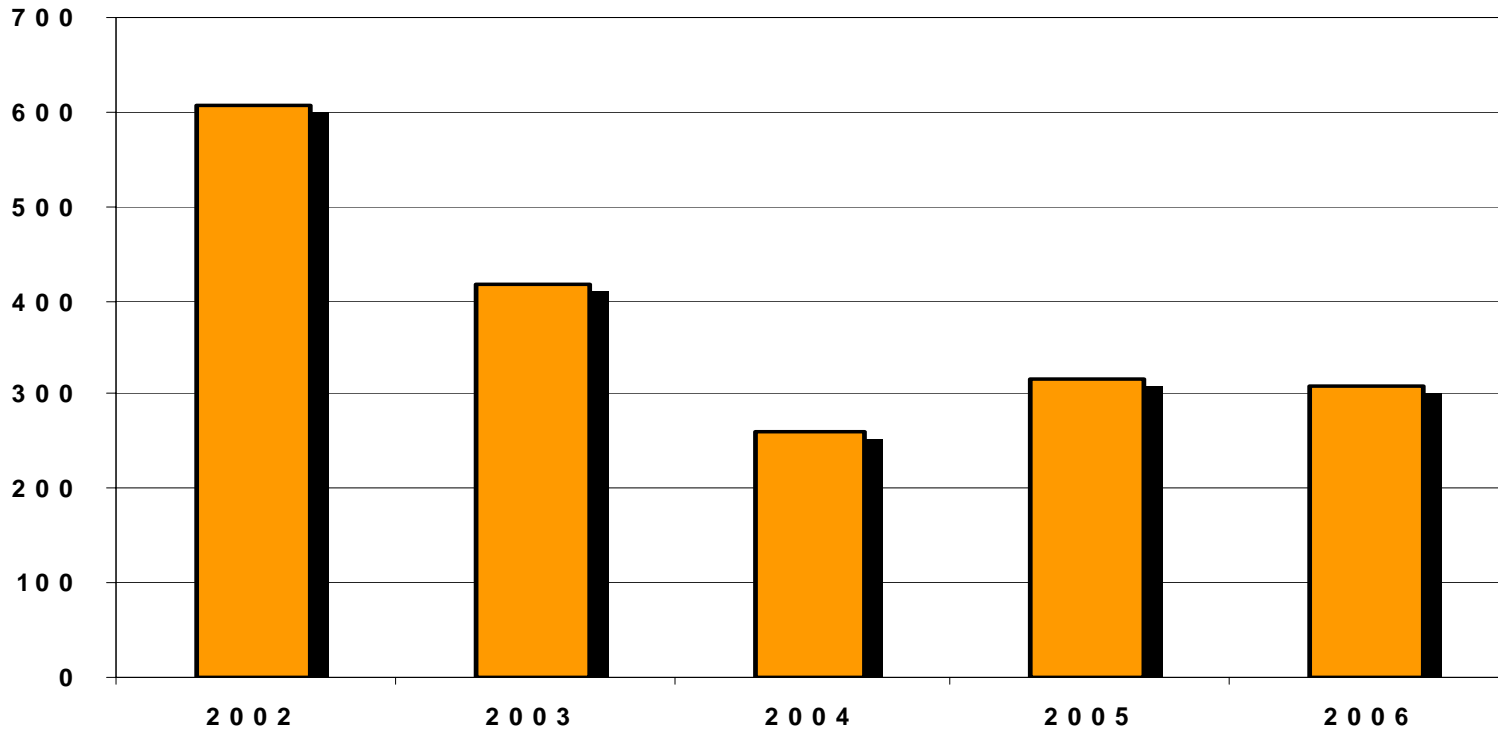
# Regulatory Actions



# Investigations



# Adverse Event Reports Calendar Year



# Adverse Event Reports by Species Calendar Year

